

UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Dean A. Schaefer et al. Confirmation No.: 9215
Serial No.: 10/774,739 Examiner: Quynh-nhu Hoang Vu
Filing Date: February 9, 2004 Group Art Unit: 3763
Docket No.: 1001.1386102 Customer No.: 28075
For: INTRAVASCULAR CATHETER WITH MULTIPLE AXIAL FIBERS

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW**CERTIFICATE FOR ELECTRONIC TRANSMISSION:**

The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 15th day of January 2010.

By



Kathleen L. Bockley

Dear Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this Request.

This Request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached arguments.

This Request is signed by an attorney or agent of record.


Respectfully submitted,

Dean A. Schaefer et al.

By their Attorney,

Date:

1/15/2010



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PRE-APPEAL CONFERENCE BRIEF**CERTIFICATE FOR ELECTRONIC TRANSMISSION:**

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By Kathleen L. Boekley
 Kathleen L. Boekley

Dear Sir:

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

Claims 16-20, 22, 24, 29-33 and 35-36 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Webster, Jr. (U.S. Patent No. 5,057,092) in view of Kaye (U.S. Patent No. 4,191,219). Applicants respectfully traverse this rejection. Nowhere do Webster, Jr. or Kaye disclose many elements of claim 16, including for example, "the reinforcement layer comprising a tubular braid having a first helical member interwoven with a second helical member forming a plurality of crossover points and a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points such that the lumen of the elongate shaft and an outer surface of the outer polymer layer are free from radial protrusions".

Instead, Webster, Jr. discloses an intravascular catheter including an elongated catheter body having a flexible plastic inner wall 22, a braided reinforcing mesh 24 surrounding the inner wall 22, and a flexible plastic outer wall 30 surrounding the reinforcing mesh 24. The braided reinforcing mesh 24 includes a plurality of interwoven helical members 26. Webster, Jr. teaches that, typically, half of the interwoven helical members 26 extend in one direction and the other half of interwoven helical members 26 extend in the counter direction. In addition, the braided

reinforcing mesh 24 includes longitudinal warp members 28. However, the longitudinal warp members 28 are not disposed between the first and second helical members 26 at each of the plurality of crossover points. Instead, at numerous crossover points, both the first and second helical members 26 are on the same side of the longitudinal warp members 28. See, for example, Figure 2. As such, Webster, Jr. does not teach or suggest the longitudinal warp members 28 disposed between the first and second helical members at each of the plurality of crossover points.

Kaye discloses a triaxial fabric for use as a needlepoint canvas with the yarns forming the fabric being defined by three sets of yarn courses with the courses within each set being parallel. The courses of each set are angular to the courses of the other two sets, usually at a 60-degree angle with the courses from all three sets commonly intersecting at a plurality of points in a repetitive pattern over the fabric. (See Abstract). Applicants respectfully assert that fabric for a needlepoint canvas formed of yarn as taught by Kaye is clearly non-analogous art.

As the Examiner is aware, a *prima facie* case of obviousness is established "when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *Application of Rinehart*, 531 F.2d 1048, 1052 (CCPA, 1976). "The reference must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned" *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). Applicants respectfully submit that fabric for a needlepoint canvas is not in Applicants' field of endeavor. Applicants' field of endeavor, as evidenced by the Field of Invention on page 1 of the present application, is intravascular catheters or, more specifically, intravascular catheters having a braid reinforcement. As Kaye is not in Applicants' field of endeavor, it must be reasonably pertinent to the particular problem with which the inventor was involved. Applicants respectfully assert that yarn for a needlepoint fabric is clearly not reasonably pertinent to axial members for a braided reinforcement layer disposed between an inner and outer polymer layer and that a person of skill in the art would not look to needlepoint fabric when designing medical devices. Further, as articulated in the Final Office Action, the reason to modify Webster, Jr. with Kaye is in order to prevent slippage, maximize tear resistance, high torsional stiffness, high resiliency and high flexibility. However, nothing in the teachings of Kaye appear to solve let alone even address these problems, as these problems do not appear to be relevant to needlepoint canvas. As such, Kaye does not appear to be reasonably pertinent to the particular problem with which the inventor was concerned. Thus,

Kaye is believed to be non-analogous art and cannot be relied upon to establish a *prima facie* case of obviousness.

Further, if Kaye is somehow considered analogous art (which Applicants believe is not), it is axiomatic that “because they can be” clearly fails to establish a proper *prima facie* case of obviousness. Under KSR, there must be some reason to make the claimed combination. The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) stated: “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. (Emphasis added) (see page 14 of the April 30, 2007 decision). The Court further stated: a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. (See page 14 of the April 30, 2007 decision). It appears that in making the rejection, the Final Office Action has merely found several elements of the claim in the prior art and has made a conclusion of obviousness without any articulated reasoning with some rational underpinning to support the conclusion. The reasoning provided in the Final Office Action to support the legal conclusion of obviousness is that “it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Webster with an interwoven cross construction, as taught by Kaye, in order to prevent slippage, maximize tear resistance, high torsional stiffness, high resiliency and high flexibility”. However, these reasons appear to come directly from Applicants’ own specification, see for example, paragraphs 13, 36-41, and 47. Applicants submit that the only motivation or reason for combining Webster, Jr. and Kaye in the manner suggested by the Final Office Action comes from Applicants' own specification, which is clearly improper.

The Final Office Action also suggests that “a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points” is an obvious design choice. Applicants respectfully disagree. Notably, the MPEP only discusses an obvious design choice with regards to rearrangement of parts. As articulated by MPEP § 2144.04(VI)(C), “the mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims ... is not by itself sufficient to support a finding of obviousness”, but that the prior art must provide a motivation or reason for the rearrangement. Applicants respectfully assert that “a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of

crossover points” is not an obvious matter of design choice or a mere rearrangement of parts, as suggested in the Final Office Action. As is readily apparent from the present specification, “a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points” may indeed modify the operation of the intravascular catheter, and may provide additional benefits over the system disclosed by Webster, Jr. For example, the claimed intravascular catheter may help maintain low friction and adequate sealing of the catheter and may reduce the chance of adjacent polymer layers becoming fixed to the axial members. As such, Applicants submit that “a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points” is not an obvious matter of design choice or a mere rearrangement of parts, as asserted in the Final Office Action. For at least these reasons, claim 16 and claims 17-20, 22, and 24, which depend from claim 16, are believed to be patentable over Webster, Jr. and Kaye.

Claims 16-20, 22, 24, 29-33, 35 and 36 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Webster (U.S. Patent No. 5,057,092) in view of Huppert (U.S. Patent No. 2,114,274). Applicants respectfully traverse this rejection. Huppert appears to disclose a tubular braid for use in the manufacture of hair dressing accessories, such as foundations, curlers, rollers, and the like. Clearly, a tubular braid for hair dressing accessories is not in Applicants’ field of endeavor. Further, similar to Kaye as discussed above, Applicants respectfully assert that hair dressing accessories are not reasonably pertinent to axial members for a braided reinforcement layer disposed between an inner and outer polymer layer and that a person of skill in the art would not look to hair dressing accessories when designing medical devices. Thus, Applicants respectfully assert that Huppert is non-analogous art and cannot be relied upon to establish a *prima facie* case of obviousness.

The Final Office Action asserts that “Huppert discloses a tubular braid for use among other purpose. In this case, a medical article such as a catheter thus is analogous in structure to tubular braid of Huppert. Therefore, the braid tubular and the catheter tube are interchangeable and can be used in catheter arts as it relates with the tubular”. Applicants disagree. As discussed above, Huppert discloses a tubular braid for hair dressing accessories, such as foundations, curlers, rollers, and the like. Clearly hair dressing accessories are not interchangeable with medical device catheters, as suggested in the Office Action. Medical device catheters are used for, for example, intravascular procedures, whereas hair dressing accessories are used generally for dressing hair. Clearly these are not interchangeable.

However, if Huppert is somehow considered analogous art (which Applicants believe is not), Applicants respectfully assert that Webster, Jr. and Huppert fail to disclose all the elements of claim 16, as admitted on page 6 of the Final Office Action, namely, "a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points". The Final Office Action, however, asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to add more axial members for the purpose of increasing the reinforcing or torsional rigidity. This is not understood. Applicants can find no reason in Webster, Jr. or Huppert for adding more axial members to modify the device of Webster, Jr. to have "a plurality of axial members disposed between the first helical member and the second helical member at each of the plurality of crossover points". In fact, the only reason appears to come from Applicants' own specification, which is clearly improper. Therefore, for at least these reasons, claim 16 and claims 17-20, 22, and 24, which depend from claim 16, are believed to be patentable over Webster, Jr. and Huppert.

Further, for additional reasons to those discussed above, Applicants respectfully refer the Panel to pages 6-15 of the Response After Final filed November 16, 2009, which Applicants hereby incorporate by reference.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Dean A. Schaefer et al.

By their attorney,

Date: _____

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